

MEMORANDUM OF AGREEMENT

This Agreement is entered into to specify the terms and conditions under which the General Hospital Corporation (doing business as Massachusetts General Hospital), hereinafter referred to as "the General," and General Electric Company, hereinafter referred to as "the Subcontractor," will participate in the conduct of a project entitled "Development and Clinical Evaluation of Tomosynthesis for Digital Mammography," under U.S. Army Medical Research Acquisition Activity (USAMRAA) Grant No. DAMD17-98-1-8309 awarded to the General effective September 24, 1998, with Daniel Kopans, M.D., as Principal Investigator for the General, and Beale Opsahl-Ong, Ph.D., as Co-Investigator for the Subcontractor.

A. Programmatic Considerations

Article 1. Period of Performance

This Agreement shall begin on January 4, 1999 and shall not extend beyond October 29, 2001 unless the period of performance is extended by modification of the Agreement.

Article 2. Statement of Work

The Subcontractor shall provide all the necessary qualified personnel, equipment, materials (except as otherwise may be provided herein) and facilities to accomplish the research tasks as set forth in the Statement of Work attached as Appendix A and Subcontractor's proposal dated September 14, 1998, as revised December 15, 1998, incorporated herein by reference. Any change in the Statement of Work must be approved by the Principal Investigator for the General and the designated Administrator for the General (see Article 10), in writing, through formal modification of this Agreement.

Article 3. Technical Reporting Requirements

Periodic Performance Report

Subcontractor shall immediately notify the Principal Investigator at the General of developments that have significant impact on the activities supported by this Agreement. Also, notification shall be given in the case of problems, delays or adverse conditions which materially impair the Subcontractor's ability to meet the objectives of the Statement of Work. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

Annual Technical Report

Subcontractor shall provide Annual Technical Reports, including a complete summary of the activities performed under this Agreement during the reporting period. Annual Reports are due on each calendar anniversary date of this agreement.

Final Technical Report

Subcontractor shall provide a Final Technical Report, including a summary of the entire effort under this Agreement, citing data in the annual reports, and providing a complete reporting of results. The Final shall replace the Annual Report in the final year of the performance period. The Final Report must be accompanied by a document showing a bibliography of all publications, presentations, and meeting abstracts supported under this Agreement, and a list of personnel supported under this Agreement. The Final Report shall be submitted within thirty (30) days of the close of the period of performance for inclusion in the Principal Investigator's Final Technical Report to USAMRAA.

Annual and Final Property Report

Within thirty (30) days of the end of each budget period, Subcontractor shall provide a list of real and personal property acquired under this Agreement in accordance with OMB Circular A-110, Sections __.31 through __.37.

Annual and Final Patent Reports - The Subcontractor shall provide Annual Patent Reports (DD882) within thirty (30) days of each anniversary date of this Agreement, and a Final Patent Report (DD882) within thirty (30) days of the close of the period of performance.

Article 4. Change of Investigators

If Beale Opsahl-Ong, Ph.D., Co-Investigator for the Subcontractor, severs his connection with the Subcontractor, or otherwise relinquishes active direction of the project (either permanently or for a continuous period of more than three (3) months or a 25 percent reduction in time devoted to the project), the Subcontractor must seek and receive prior approval from the General for a change in key personnel or key personnel effort. In the case of change in key personnel, the decision as to the continuance of this Agreement shall be made by the General on the basis of information supplied by the Subcontractor.

The Subcontractor shall not transfer, by contract or other means, a significant portion of the programmatic effort under this Agreement without prior approval of the Administrator for the General.

Article 5. Site Visits

The USAMRAA, through authorized representatives, has the right, at all reasonable times, to make site visits to review project accomplishments and to provide such technical assistance as may be required. If any site visit is made by USAMRAA on the premises of the Subcontractor, the Subcontractor shall provide all reasonable facilities and assistance for the safety and convenience of the Government representatives in the performance of their duties. All site visits and evaluations shall be performed in such a manner as will not unduly interfere with or delay the work.

Article 6. Termination

This Agreement may be terminated in whole or in any of the following cases:

- a) If the Subcontractor materially fails to comply with the terms and conditions of this Agreement. Action by the General to suspend or terminate this Agreement for cause will be taken only after the Subcontractor has been informed by the General of any deficiency on its part and given an opportunity to correct it. However, the General may immediately suspend or terminate this Agreement without prior notice when it believes such action is necessary to protect the interests of the USAMRAA.
- b) By mutual agreement, in which case the two parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated.
- c) In the event that USAMRAA terminates Grant No. DAMD17-98-1-8309 to the General.

In the event of termination, costs incurred by Subcontractor after termination, which are necessary and not reasonably avoidable, are allowable if:

- a) The costs result from obligations which were properly incurred by the Subcontractor before the effective date of suspension or termination, are not in anticipation of it, and in the case of a termination are noncancellable; and
- b) The costs would be allowable if the Agreement were not suspended or expired normally at the end of the funding period in which the termination takes effect.

B. Fiscal Considerations

Article 7. Consideration, Payment and Requests for Prior Approval

The amount of \$232,250 is authorized for the direct costs of the research and for indirect costs \$381,739 (total cost ceiling \$613,989). (See budget detail in Appendix B attached hereto.) The allowability of costs incurred is determined in accordance with the provisions of the Federal Acquisition Regulation (FAR) at 48 CFR part 31, "Contract Cost Principles and Procedures."

Actual payments shall be made to the Subcontractor within the total costs so authorized upon receipt of monthly or quarterly invoices for costs incurred. Invoices must reference Grant No. DAMD17-98-1-8309 and be submitted to the Principal Investigator at the General for approval. (See Article 10.) Approved invoices will be forwarded to the General's assigned Grant Management Specialist for payment. The format for invoice submission appears as Appendix C. The Subcontractor shall maintain a financial management system that complies with the standards of OMB Circular A-110, "Standards for Financial Management Systems," Section __21.

The Subcontractor shall obtain the prior approval of the General for costs that require prior approval in accordance with 48 CFR part 31, "Contract Cost Principles and Procedures." Requests for prior approval shall be directed to the designated Administrator for the General. Such requests will be reviewed and, as appropriate, approved by the General.

Costs shall not be incurred for the following, and any such costs incurred may not be reimbursed, unless prior written approval is obtained from the Administrator for the General:

- (a) Foreign travel not specifically identified in the approved budget incorporated as Attachment B;
- (b) General purpose equipment;
- (c) Equipment exceeding \$5,000 not specifically identified in the approved budget incorporated as Attachment B;
- (d) Alterations and Renovations not specifically identified in the approved budget incorporated as Attachment B.

The Subcontractor shall maintain a procurement system which, at a minimum, meets the requirements of OMB Circular A-110, "Procurement Standards," Sections __.40 through __.48.

The Subcontractor may be reimbursed at indirect cost rates no higher than those approved by the cognizant audit agency. Should the Subcontractor's rate(s) increase during the period of this Agreement, the General is under no obligation to provide supplemental funding.

Article 8. Audits and Records

Financial records, supporting documents, statistical records, and other records pertinent to each year of this Agreement shall be retained by the Subcontractor for a period of three (3) years from payment of the Subcontractor's final invoice, or, for indirect cost computation supporting records, three (3) years from the date of submission of the indirect cost rate computation or proposal to the cognizant Federal agency. Records that are the subject matter of audits, appeals, litigation, or the settlement of claims arising out of the performance of the Agreement shall be retained until such audits, appeals, litigation, or claims have been disposed of, or until the end of the regular three-year retention period, whichever is later.

Unless court actions or audit proceedings have been initiated, the Subcontractor may substitute copies made by microfilming, photocopying, or similar methods for the original records.

The head of USAMRAA, the Comptroller General of the United States, the General, or any of their duly authorized representatives, shall have access to any pertinent books, documents, papers, and records of the Subcontractor organization, to make audits, examinations, excerpts and transcripts. Further, any negotiated contract in excess of \$10,000 made by the Subcontractor shall include a provision to the effect that the USAMRAA, the Comptroller General, or any of their duly authorized representatives, shall

have access to pertinent records for similar purposes. The rights of access to records in this paragraph shall not be limited to the required retention period, but shall last as long as the records are retained.

Records for real property and equipment acquired under this Agreement shall be retained for three (3) years after final disposition.

Article 9. Final Invoice

The Subcontractor shall submit annual financial reports of expenditures to the General within sixty (60) days of the close of each budget period in the same format as Appendix C.

C. Additional Provisions

Article 10. Administrative and Technical Personnel

For purposes of this Agreement, Barbara Steele, Research Grant and Contract Specialist, is designated as Administrator for the General and shall be contacted for resolution of fiscal and administrative questions. Daniel Kopans, M.D., Principal Investigator for the General, shall be contacted for resolution of technical questions.

Property and Patent reports shall be delivered to the Administrator for the General. All other Technical Reports and Invoices shall be delivered to the Principal Investigator for the General.

Barbara Steele, Research Grant/Contract Specialist
Massachusetts General Hospital
Research Management (BAR-305)
55 Fruit Street
Boston, MA 02114
Phone (617)724-2725 FAX (617)726-2796

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Massachusetts General Hospital
Radiology-Breast Imaging Division (WACC 219)
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Article 11. Equipment Accountability and Disposition

Title to equipment purchased or fabricated under this Agreement, and in any lower tier contract under this Agreement, resides with the General upon acquisition. Therefore, the General will have a continuing responsibility for the inventory, accountability and disposition of equipment purchased under this Agreement. The Subcontractor shall maintain a property management system which, at a minimum, meets the requirements of OMB Circular A-110, "Property Standards," Sections ____30 through ____37.

A listing of all equipment with a unit cost greater than \$5,000 acquired or fabricated under this Agreement must be submitted to the Administrator for the General within thirty (30) days of the close of the period of performance so that it may be included with the General's final report to USAMRAA.

Article 12. Publications and Copyrights

The investigators are expected to publish or otherwise make publicly available the results of the work conducted under this Agreement. The Principal Investigator at the General and the Co-Investigator for the Subcontractor shall together make decisions regarding authorship on research and other publications. A copy of each manuscript or subsequent reprints of any publication resulting from the research must be provided to the General for submission to USAMRAA.

An acknowledgment of awarding agency support and a disclaimer must appear in the publication of any material, whether copyrighted or not, based on or developed under this project, in the following terms: "This material is based upon work supported by the USAMRAA under Award No. DAMD17-98-1-8309."

All materials, except scientific articles or papers published in scientific journals, must also contain the following: "Any opinions, findings, and conclusions or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the USAMRAA."

Article 13. Public Releases

Prior to release to the public, the Subcontractor shall notify the General, who will notify the USAMRAA, of the following: planned news releases, planned publicity, advertising material concerning work under this Agreement, and planned presentations to scientific meetings. This provision is not intended to restrict dissemination of research information; the purpose is to inform the USAMRAA of planned public release of information on USAMRAA-funded research, in order to adequately respond to inquiries and to be alert to the possibility of inadvertent release of information which could be taken out of context.

Article 14. Inventions and Patents

The determination of the rights of ownership and disposition of inventions resulting from the performance of the research under this Agreement shall be in accordance with Federal Acquisition Regulation clause 52.227-12 "Patent Rights--Retention by the Contractor (Long Form)." The Subcontractor shall ensure that this policy is applicable to all persons who perform any part of the work under this Agreement and who may be reasonably expected to make inventions.

The Subcontractor shall use DD Form 882, Report of Inventions and Subcontracts, for disclosure of patents and inventions. Negative reports are required. See Article 3 - "Technical Reporting Requirements" for specific reporting deadlines.

Article 15. Rights in Technical Data and Computer Software

Rights in technical data and computer software under this Agreement shall be as specified in the Defense FAR Supplement (DFARS) 252.227-7013, "Rights in Technical Data--Noncommercial Items" dated NOV 1995 and 252.227-7014, "Rights in Noncommercial

Computer Software and Noncommercial Computer Software Documentation" dated JUN 1995, which are incorporated by reference.

Article 16. Use of U.S.-Flag Air Carriers

In the event that foreign travel is approved specifically approved under this Agreement, Subcontractor shall comply as follows:

- a. The Comptroller General of the United States, by Decision B138942 of June 17, 1975, as amended March 31, 1981, provided guidelines for implementation of Section 5 of the International Air Transportation Fair Competitive Practices Act of 1974.
- b. Any air transportation to, from, between, or within a country other than the U.S., of persons or property, the expense of which will be covered under this Agreement, must be performed on a U.S.-flag air carrier if service provided by such carrier is "available."
- c. The following rules apply unless the result would be use of a foreign air carrier ("foreign carrier") for the first or last leg of travel from or to the U.S.:
 - (1) A U.S.-flag air carrier ("U.S. carrier") shall be used to destination or, in the absence of through service, to farthest interchange point.
 - (2) If a U.S. carrier does not serve an origin or interchange point, a foreign carrier shall be used to the nearest interchange point to connect with a U.S. carrier.
 - (3) If a U.S. carrier involuntarily reroutes the traveler via a foreign carrier, the foreign carrier may be used.
- d. Exceptions. In the following situations, use of a foreign carrier is permissible:
 - (1) Travel to and from the U.S. Use of a foreign carrier is permissible if:
 - (a) The airport abroad is the origin or destination airport, and use of a U.S. carrier would extend the total travel time 24 hours or more than would travel by foreign carrier; or
 - (b) The airport abroad is an interchange point, and use of a U.S. carrier would require the traveler to wait six (6) hours or more to make connection or would extend the total travel time six (6) hours or more than would travel by foreign carrier.
 - (2) Travel Between Points Outside the U.S. Use of a foreign carrier is permissible if:
 - (a) Travel by foreign carrier would eliminate two (2) or more aircraft changes en route; or
 - (b) Travel by U.S. carrier would extend the total travel time six (6) hours or more than would travel by foreign carrier.
 - (3) Short Distance Travel. For all short distance travel, regardless of origin and destination, use of a foreign carrier is permissible if the elapsed travel time on a

scheduled flight from origin to destination airport by foreign carrier is three (3) hours or less and service by U.S. carrier would double the travel time.

Article 17. Contract Work Hours and Safety Standards Act

Subcontractor shall comply with Sections 102 and 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-333), as supplemented by Department of Labor regulations (29 CFR part 5).

D. Required Assurances

Article 18. Use of Human Subjects and Use of Human Anatomical Substances

The Subcontractor shall not conduct any research under this Agreement involving humans as research subjects or human anatomical substances without prior written approval of the authorized institutional official at the General and formal modification of this Agreement.

Article 19. Protection of Animal Welfare

The Subcontractor shall not conduct any research under this Agreement involving laboratory animals without prior written approval of the authorized institutional official at the General and formal modification of this Agreement.

Article 20. Civil Rights and Equal Employment Opportunity

The Subcontractor shall comply with E.O. 11246, "Equal Employment Opportunity," as amended by E.O. 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and as supplemented by regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor." This Agreement is subject to the provisions of Title IV of the Civil Rights Act of 1964 (P.L. 88-352), Title IX of the Education Amendments of 1972 (P.L. 92-318, 20 USC 1681 et seq.), Section 504 of the Rehabilitation Act of 1973 (29 USC 794), and the Age Discrimination Act of 1975 (P.L. 94-135).

Article 21. Clean Air Act

Subcontractor shall comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. 7401 et seq. and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251 et seq.).

Subcontractor agrees: that no portion of the work under this Agreement will be performed in a facility listed on the Environmental Protection Agency (EPA) List of Violating Facilities on the date that this Agreement was effective unless and until the EPA eliminates the name of such facility or facilities from such listings; to use its best efforts to comply with clean air standards and clean water standards at the facility in which the Agreement is being performed; to insert the substance of the provisions of this clause into any nonexempt subaward or contract under this Agreement; and to report violations to the federal awarding agency and the Regional Office or the Environmental Protection Agency.

Article 22. Debarment and Suspension

The Subcontractor certifies to the best of its knowledge and belief that neither it nor its principal employees are presently debarred, suspended, or proposed for debarment or declared ineligible for the award of subcontracts, by any Federal Agency, in accordance with OMB Circular A-110.

Article 23. Certification of Non-Delinquency on Federal Debt

The Subcontractor certifies that it is in compliance with the Non-Delinquency on Federal Debt criteria, in accordance with OMB Circular Number A-129.

Article 24. Certification of Drug-Free Workplace

The Subcontractor certifies that it has implemented appropriate policy in accordance with the Drug-Free Workplace Act of 1988, 45 CFR Part 76, Subpart F.

Article 25. Misconduct in Science

The Subcontractor certifies that it is in compliance with PHS policy concerning "Initial Assurance Regarding Procedures for Dealing with and Reporting Possible Misconduct in Science" (Form PHS 6315).

Article 26. Certification Regarding Lobbying

The Subcontractor certifies that it is in compliance with the Byrd Anti-Lobbying Amendment, Section 1352, Title 31, U.S. Code with regard to this Agreement.

E. Other Assurances

The Subcontractor hereby acknowledges that all employees hired by it, under or as a result of this Agreement, shall, during the term of this Agreement, be deemed to be employees of the Subcontractor and at no time be considered employees of the General and, therefore, not entitled to any retirement or other fringe benefits from the General.

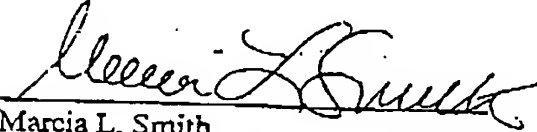
The Subcontractor shall pay all debts for labor and materials contracted for by it, and for the rental of appliances and equipment hired by it, for and on account of, the work to be performed hereunder. The Subcontractor shall conform to all requirements of law and all other public authorities, state or local, relating to the methods or materials to be used or to the persons to be employed in doing the work.

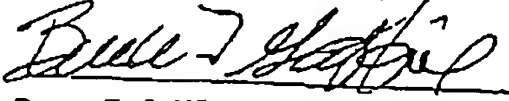
The Subcontractor shall hold the General and its employees harmless from any and all liability of every nature and description arising out of this Agreement including but not limited to damage to property or personal injuries including death to the extent caused by the negligence or willful misconduct of Subcontractor or its employees or agents in performing its services under this Agreement, or the breach of this Agreement by Subcontractor, its employees or agents.

The Subcontractor agrees that acceptance of the final invoice payment from the General hereby releases and forever discharges the General of and from all claims, demands and liabilities whatsoever of every name and nature both at law and in equity.

The General Hospital Corporation
d/b/a Massachusetts General Hospital

General Electric Company


Marcia L. Smith
Director for Proposal
and Award Management


Bruce F. Griffing
Manager, Industrial Electronics Laboratory
GE-Corporate Research & Development

1/13/1999
Date

1/20/99
Date

MEMORANDUM OF AGREEMENT

Between the General Hospital Corp. and General Electric Company

APPENDIX A

STATEMENT OF WORK

Task 1 - Develop tomosynthesis system. (months 1-9)

- 1.1 Design and fabricate hardware and write software for automated motion of the x-ray source. (months 1-6)
- 1.2 Acquire hardware and write software for fast data acquisition. (months 1-6)
- 1.3 Write software for image reconstruction and display. Viewer will be able to step through images or view on a continuous "cine" loop. (months 1-6)
- 1.4 Develop image processing algorithms for minimizing presence of out of plane structures in images. (months 1-9)
- 1.5 Integrate, test, and validate system. (months 4-9)
- 1.6 Perform safety, reliability, and performance tests on system before clinical implementation. (months 7-9)

Task 2 - MGH preliminary patient study. (months 10-15)

- 2.1 Upgrade FFDM system at MGH for tomosynthesis capability and train MGH personnel. (month 10)
- 2.4 Using feedback from patient images, optimize image processing algorithms for minimizing presence of out-of-plane structures in images. (months 11-15)
- 2.5 Provide system support and maintenance. (months 10-15)

Task 3 - Upgrade/install system at MGH. (months 10-16)

- 3.1 Upgrade FFDM system at MGH for clinical tomosynthesis capability and train MGH personnel. (month 15)
 - 3.1.1 Hardware/software for automated motion of the x-ray source. (months 10-15)
 - 3.1.2 Hardware/software for fast data acquisition. (months 10-15)
 - 3.1.3 Software for image reconstruction and display. Viewer will be able to step through images or view a continuous "cine" loop. (months 10-15)
 - 3.1.4 Integrate, test, and validate systems. (months 13-15)
 - 3.1.5 Perform safety, reliability, and performance tests on systems before clinical installation. (months 13-15)

Task 4 - Clinical trial of tomosynthesis. (months 13-36)

- 4.4 Provide support and maintenance for tomosynthesis components of clinical systems. (months 13-36)

Task 5 - Data analysis and conclusions. (months 16-36)

Participate in the data analysis and conclusions efforts based on the clinical studies.

MEMORANDUM OF AGREEMENT

Between the General Hospital Corp. and the General Electric Company

APPENDIX B**BUDGET FOR THE PERIOD**

January 4, 1999 - January 3, 2000

Personnel	\$225,679
Supplies	\$ 5,386
Travel	<u>\$ 1,185</u>
Total Direct Costs	\$232,250
Indirect Costs	<u>\$381,739</u>
Total Costs	<u>\$613,989</u>

MEMORANDUM OF AGREEMENT

Between the General Hospital Corp. and the General Electric Company

APPENDIX C

FORMAT FOR INVOICES

Subcontractor Institution

Address

TO: *

Total Allocation \$

GRANT NO.

DATE OF INVOICE

REIMBURSABLE COSTS FOR THE PERIOD TO

<u>CATEGORY</u>	<u>CURRENT PERIOD</u>	<u>TO DATE</u>
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Salaries and Wages	\$	\$
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Applicable Fringe Benefits

Equipment

Supplies

Travel

Other Expense

Total Direct Cost

Indirect Cost

Total Billed

Less Amount Previously Billed

Total Billed Current Period

By

Title

Date

*Invoices should be sent to the Principal Investigator who will review, approve and send them to the assigned Grants Management Specialist for payment.